REMARKS

The Examiner is thanked for the due consideration given the application.

Claims 21-28, 36 and 41-43 are pending in the application. The independent claims have been amended to set forth the present invention. New claims 41 and 42 set forth that the molding is injection molding.

No new matter is believed to be added to the application by this Amendment.

Rejections Based on Cougoulic

Claims 21-24, 26 and 27 have been rejected under 35 USC §103(a) as being unpatentable over Cougoulic (U.S. Patent 5,872,159) in view of Mills et al. (U.S. Patent 6,482,584).

Claim 25 has been rejected under 35 USC §103(a) as being unpatentable over Cougoulic in view of Mills et al., and further in view of Ellingsen et al. (U.S. Publication 2002/0111694).

Claims 28 and 36 have been rejected under 35 USC §103(a) as being unpatentable over Cougoulic (U.S. Patent 5,872,159) in view of Mills et al. (U.S. Patent 6,482,584).

Claim 41 has been rejected under 35 USC §103(a) as being unpatentable over Cougoulic (U.S. Patent 5,872,159) in view of Mills et al. (U.S. Patent 6,482,584).

These rejections are respectfully traversed.

Before considering the applied art, the applicant believes that the field and technical goal of the present invention should be reviewed in order achieve full appreciation of the inventive technology.

1.1. The prerequisites for an efficient osteo-integration

Although it is known that tricalcium phosphate and/or other osteo-inductive materials favor osteo-integration, using a material formed from such compounds is not enough to get an efficient and quick osteo-integration of the implant into the bone. At least two other conditions must be met:

1. the osteo-inductive compound must be active at the surface of the implant, that is, it must be found at the surface, touching the tissue with a bare face, i.e., the compound should not be covered with a binder layer or veil; and

2. the surface touching the tissue shall be micro textured, with micro pores "sucking up" cells and organic liquids and providing a mechanical micro anchoring of the bone to the implant material.

This is known from prior art. Ideally the osteo-inductive components should lie in the micro pores.

1.2 Technical problem statement

The main technical problem is to achieve such a surface condition in a molded piecework, more specifically when this molded piecework is of small dimension such as a dental implant.

Micro pores cannot be produced by the molding process. Such a micro pattern would be difficult to cut even by micro machining either of the implant or of the mould. Furthermore, if cut on the mould surface, such a pattern would impede a smooth material flow during the injection process thus leading to an uneven filling of the mould. Basically, the surface of the mould should be mirror polished and so is the surface of the implant just after the injection molding process.

The molding process is made under high temperature and high pressure conditions (150 to 300 bars, 2200 to 2500 PSI), therefore as the material in a doughy state is pressed against the stamp surface, compound particles that are closed to the surface are either crushed and/or buried beneath said surface. There is no way to get emerging crystals through such a molding process although one cannot exclude to get some of them by chance.

Just after molding, the surface of the piecework is smooth with some compounds embedded in it. However since the implant might be contaminated by metallic particles, e.g., steel particles coming from the injection screw or from the mold, implants must be pickled in HCl or H_2SO_4 in order to eliminate such particles. This pickling process is actually an etching one because the particles embedded in the piecework surface are dissolved by the HCl, leaving micro holes or pores at the place they were formerly embedded.

Following such an etching, the surface of the implant is no more active since all the osteo-inductive components have been removed from it.

Therefore the overall technical problem should be stated as follows:

To make a molded implant with a biologically active and uncontaminated micro textured surface.

1.3 Inventive solution

In order to biologically activate the surface, a further etching with acetone is performed. The combination of acetone with ultrasonic sonication etches a layer of the binder (e.g., PEEK) without etching the osteo-inductive compounds. The previously formed pores are, at least partially, removed with the PEEK layer etched by acetone. At the end of this process, followed by well known sterilization steps, the surface of the implant is smooth with emerging osteo-inductive compound particles.

These particles can be crystallized by subjecting the piecework to temperature and pressure in an autoclave. This crystallization increases the exchange area of the osteo-inductive compounds thus enhancing their effect and accelerating the osteo-integration process.

After insertion of the implant in the tissue these crystals are resorbed, leaving micro pores where they were

initially laying, thus promoting cells colonization and anchoring.

Figure 1 below shows schematically the surface of the implant after each step.

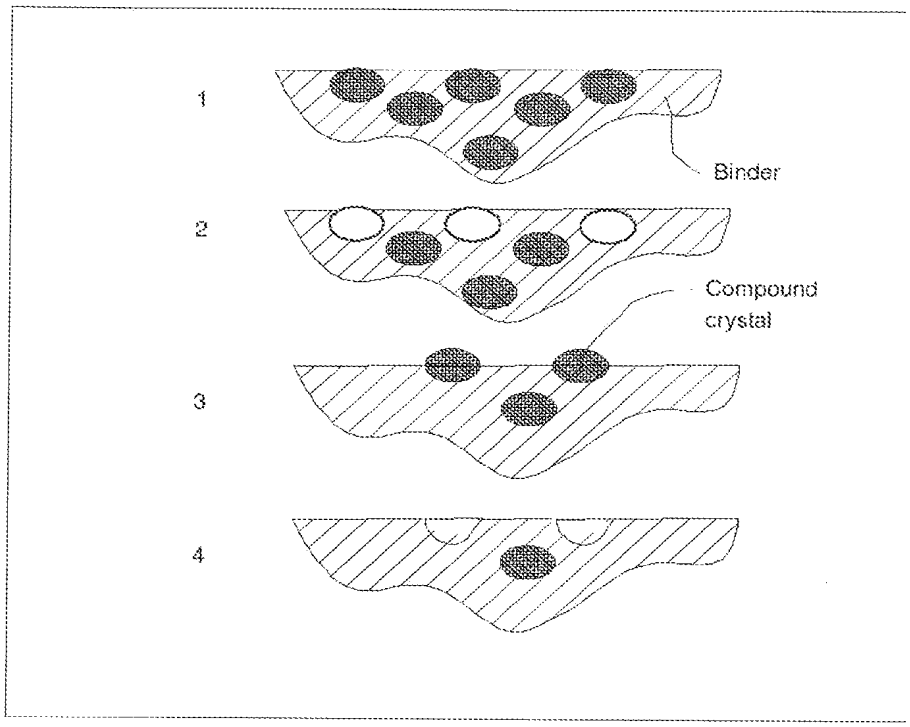

Figure 1: Evolution of surface conditions according to each step of the process :1: as molded, 2: Acid etching, 2: aceton etching, 4 after embeding in the tissuee and resorption of crystals

Compared with prior art, as the required microtextured surface of the implant cannot be created by conventional chemical etching or shot blasting, it is created *in situ* after insertion of the implant in the tissue.

2. Application content

The above described process is disclosed in the patent application, however some parts may lack complete clarity, but would still be clear to one of skill in the art. For example, the

French word “décapage” has been translated as “pickling” and not by “etching” which would have been more appropriate, the problem being that this French word means both. The etching protocol is however clearly stated in paragraphs [0045] to [0056] of the published US pending application.

The formation of micro porosities after embedding of the implant in the tissue is also disclosed in paragraphs [0057] and [0058] of this application. Lack of clarity may also arise from paragraph [0008] of this application where it is stated that the pickling ensures surface “application” of elements added to the binder, which tends to indicate that the pickling adds or migrates such elements to the surface.

Nevertheless, Applicant believes that the application discloses the actual process as invented. This process, as exemplarily illustrated in Figure 1 above, is clear and practicable by one of skill from the disclosure of the present application.

3. Analysis of Applied Art

3.1 Cougoulic

Cougoulic discloses a material suitable for making an implant and the process for obtaining such material. The material is a composite made of a PEEK binder and formed from compounds. Cougoulic does not teach how to make an implant, ready for implantation, out of this material except the first step, i.e., the molding process. After molding, such an implant

will have a smooth surface (at a micro scale) reproducing the mirror polished surface of the mould. Although this raw part might have some calcium phosphate compounds close to the surface, it will not exhibit emerging ***crystals***, as discussed above.

3.2 Mills et al.

Mills et al. teach a method for cleaning and sterilizing a piece of bone. The main technical problem with such a cleaning, as shown for instance by Mills in Figure 1 of this patent (reproduced below), is to soak the cleaning solutions into the microporosities of the removed piece of bone. Such porosities do not exist in the "as molded implant", exhibiting a smooth, mirror polished surface. Therefore there is no reason why a person having ordinary skill would apply the teaching of Mills et al. for cleaning such an implant.

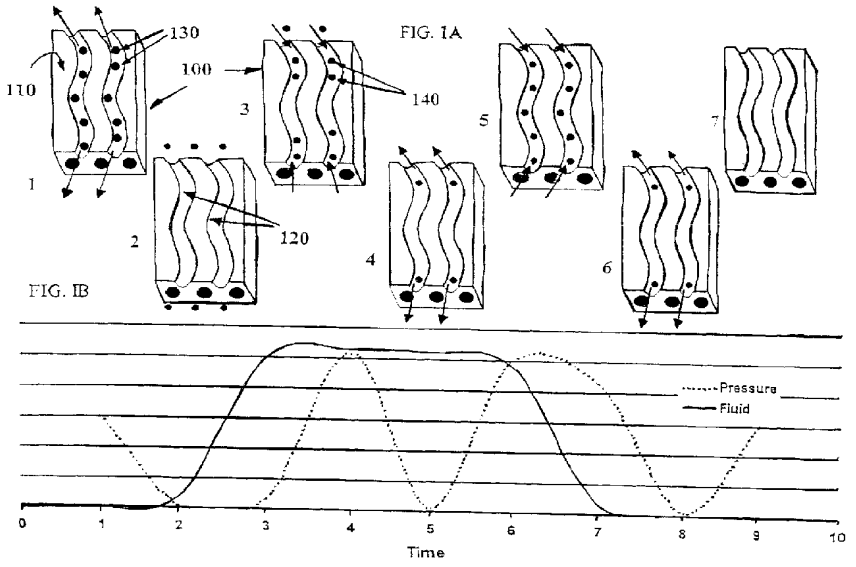

Figure 1

Even if this person would apply such teaching, Mills et al. do not teach that HCl etching should be used before an acetone etching, and this last before the autoclave treatment, i.e., Mills et al. do not teach a protocol as described in paragraphs [0045] to [0056] of the specification (US Publication).

Supposing that the acetone etching is performed before the acid etching, this would result in a surface free from calcium phosphate particles and will not lead to the expected result.

Note that Mills et al. teach a first step of subjecting the piecework to a low pressure (e.g. vacuum) in order to drain organic products out of the pores. This is the first step of any combination of Mills et al. baths or treatments. Even if the implant of the invention exhibits a sculptured surface (like a dental implant) the corresponding relief is a macro pattern with an interstitial length and a depth in the range of a millimeter for which such vacuum treatment is nonsense. Therefore if the PHOSITA does not consider the first essential step of Mills et al.s' process there is no reason why she should take into account the further steps of this method. And even if she does, considering Table II of Mills, leads to at least 9240

possible combinations[1] among which only one will give the appropriate result. Furthermore HCl and acetone are members of the same group "J" of table II, therefore they are considered by Mills to be alternatives and not to be combined. A probability of 1 out of 10,000 that the ordinary skilled person would actually arrive to the invented protocol considering Mills et al.s' teaching shows that such an occurrence is beyond reasonable belief.

Moreover, in Table II of Mills et al. the list of compounds for fluid J include acetone and HCl, but there was no indication of any order of using these materials. It is additionally notable that fluid F list Guanidine HC1, but this is clearly the hydrochloride salt of Guanidine and is not equivalent to HCl (hydrochloric acid).

Furthermore, even if this person gets the right protocol from a chemical point of view according to Mills et al.s' teaching, she will not have the physical one, since the crystallization of the surface compounds is obtained by the autoclave treatment under positive pressure. Step 4' of Mills et al.s' table II teaches either positive or negative pressure for this last step. As a consequence, the only way

[1] Mills teaches three steps, with FGHIJ, J corresponding to 18 possible products, therefore the overall possible combinations would be 22^3=10648. However, one should consider that the PHOSITA would not consider using the same bath in 2 subsequent steps. Therefore the potential combinations are 22x21x20=9240.

to arrive to the present invention's protocol starting from Mills et al.s' teaching is impermissible hindsight.

3.3 Ellingsen et al.

This patent discloses an electrolysis process using electrolytes formed from acids . . . this process is used to cover implants made of metals with a hybrid phase containing osteoinductive compounds. It is basically a coating process and has no relevance to the present invention.

4. The Combination

In light of the above, one of ordinary skill and creativity would not produce a claimed embodiment of the present invention from a knowledge of the applied art references. That is one of skill would not produce a molded piecework of the claimed materials and percentages that would produce emerging crystals. Neither would one of skill utilize the order of process steps, i.e., the baths in order. A prima facie case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

The rejections are believed to have overcome obviated or rendered moot, and no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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